

K053420

510(k) SummarySubmitter Information

Tenacore Holdings, Inc
647 E. Young Street
Santa Ana, CA 92705

NOV 15 2006

Contact

Brand Caso, QA Director Ph: 714-444-4643 Fx: 714-549-7835

Date Prepared

November 1, 2005

Product Name

SpO2 Sensor (accessory to pulse oximeter)

Predicate Device

K973970, K002223

Product Description

SpO2 sensors are electro-optical sensors that function without skin penetration, electrical contact, or heat transfer. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The optical components are housed in soft pad with a clear window. The sensor cable is terminated in a connector that couples with the corresponding monitor.

Intended Use

SpO2 Sensors are indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring.

Comparison to Predicate Device

	Tenacore Model	Epic SPo2 Finger Sensor	Medical Cables Spo2 Finger Probes
Intended use	Continuous SPO ₂ monitoring	Same	Same
Patient population (weight range)			
Anatomical sites	Finger	Finger	Finger
Patient use/reuse	Reuse	Same	Same
Sterility	Non-sterile	Same	Same
Description of patient attachment	Finger clip	Same	Same

Connector design	Various; modular or molded	Same	Same
Cable structure	Multi-conductor, shielded, PVC jacket	Same	Same
Cable length	3-12 ft	Same	Same
LED wavelength	660/895 nm 660/940 nm	Same	Same
Photodiode active area	3 mm ² , 8mm ²	Same	Same
Accuracy (Arms)	Acceptability within $\pm 3\%$	Same	Same

Performance Data & Conclusions

Performance testing was conducted during clinical hypoxia studies conducted in an independent research lab. Subject sensors were compared to arterial blood samples analyzed on a laboratory co-oximeter and found to be equivalent to predicate device accuracy claims. Bench testing was performed to verify pulse rate accuracy.

Biocompatibility, electrical safety, and EMC testing was also performed to demonstrate conformance with established industry standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Brand Caso
Quality Assurance Director
Tenacore Holdings, Incorporated
647 E. Young Street
Santa Ana, California 92705

NOV 15 2006

Re: K053420

Trade/Device Name: SpO₂ Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 8, 2006
Received: November 8, 2006

Dear Mr. Caso:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

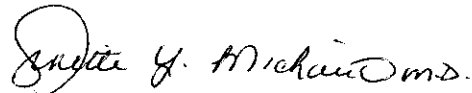
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: SpO2 Sensors

Indications for Use:

Accessory to pulse oximeter for the purpose of continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring.


Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(on Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
Device Number: K05 3420